

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,)
)
Plaintiffs,)
)
v.) C.A. No. 14-829 (SLR) (SRF)
)
ACTAVIS ELIZABETH LLC,)
)
Defendant.)

JOINT CLAIM CONSTRUCTION STATEMENT

Pursuant to the April 30, 2015 stipulated amendment to the Scheduling Order, Plaintiffs Orexo AB and Orexo US, Inc. (“Plaintiffs” or “Orexo”) and Defendant Actavis Elizabeth LLC (“Defendant” or “Actavis”) submit this Joint Claim Construction Statement for United States Patent Nos. 8,454,996 (“the ’996 Patent”) and 8,940,330 (“the ’330 Patent”).

The parties previously submitted a Joint Claim Construction Statement (D.I. 44) that included the parties’ constructions for ’996 Patent language on March 27, 2015. The ’330 Patent was subsequently added to this litigation and the parties exchanged proposed terms and constructions for the ’330 Patent on May 20, 2015. The parties include the ’996 Patent terms for construction herein for the Court’s convenience. The Court need only refer to this Joint Claim Construction Statement for the parties’ proposed constructions for all patents-in-suit.

The parties’ agreed constructions and remaining disputed constructions are provided below for each asserted patent.

I. The '996 Patent (U.S. Patent No. 8,454,996)

A. Agreed Constructions

'996 Claim Terms	Agreed Construction
“admixed with” <i>(claim 1)</i>	Mixed with.
“essentially water free” <i>(claim 2)</i>	A water content that does not prevent the bio/mucoadhesion promoting properties in a pharmaceutical composition for sublingual administration.
“bioadhesion and/or mucoadhesion promoting agent” <i>(claims 1, 2)</i>	A substance that is effective in making the active agent adhere to a mucous membrane or a mucosa (such as in the oral cavity). Microcrystalline Cellulose ('MCC') is not a bioadhesion and/or mucoadhesion promoting agent.
“sublingual administration” <i>(claims 1, 2)</i>	Placing under the tongue.
“exterior surfaces” / “surfaces” <i>(claims 1, 2)</i>	Outside part or layer.
“adhered to” <i>(claim 2)</i>	Attached at.
“microparticles” <i>(claims 1, 2)</i>	Particles in the 1 to 1000 micrometers (microns) range.

B. Disputed Constructions

'996 Claim Terms	Orexo's Proposed Construction	Actavis's Proposed Construction
“carrier particles” <i>(claims 1, 2)</i>	In the context of the claims, particles comprising one or more pharmaceutically acceptable substances, at or near the surfaces of which may be other particles.	pre-formed particles comprising one or more pharmaceutically acceptable substances, attached to the surfaces of which are other particles.
“presented at the exterior surfaces of the carrier particles” <i>(claim 1)</i>	Positioned at the outside part or layer of the carrier particles.	Admixed for a sufficiently long time to cover or affix to the outside part or layer of a pre-formed carrier particle.

'996 Claim Terms	Orexo's Proposed Construction	Actavis's Proposed Construction
“effective amount” <i>(claim 2)</i>	An amount that elicits a (i.e., is capable of conferring a desired) therapeutic response or effect.	An amount that elicits a therapeutic response.

II. The '330 Patent (U.S. Patent No. 8,940,330)

A. Agreed Constructions

'330 Claim Terms	Agreed Construction
“sublingual administration” <i>(claim 1)</i>	(Same as '996 patent above) Placing under the tongue.
“surface” <i>(claim 1)</i>	(Same as '996 patent above) Outside part or layer.
“microparticles” <i>(claims 1, 2, 8, 10)</i>	(Same as '996 patent above) Particles in the 1 to 1000 micrometers (microns) range.

B. Disputed Constructions

'330 Claim Terms	Orexo's Proposed Construction	Actavis's Proposed Construction
“carrier particles” <i>(claims 1, 3-6, 10)</i>	(Same as '996 patent above) In the context of the claims, particles comprising one or more pharmaceutically acceptable substances, at or near the surfaces of which may be other particles.	(Same as '996 patent above) pre-formed particles comprising one or more pharmaceutically acceptable substances, attached to the surfaces of which are other particles
“presented upon the surface of carrier particles” <i>(claim 1)</i>	Positioned at the outside part or layer of the carrier particles.	Affixed to the outside part or layer of carrier particles.
“pharmacologically -effective amount” <i>(claim 1)</i>	(Same as “effective amount” in '996 patent above) An amount that elicits a (i.e., is capable of conferring a desired) therapeutic response or effect.	(same as “effective amount” in '996 patent). An amount that elicits a therapeutic response.

'330 Claim Terms	Orexo's Proposed Construction	Actavis's Proposed Construction
<p>“wherein microparticles of buprenorphine or a pharmacologically-acceptable salt thereof are <u>in contact with</u> particles comprising citric acid, wherein the buprenorphine or pharmaceutically acceptable salt thereof and the citric acid are <u>not in the same particle.</u>”¹</p> <p>(claim 1)</p>	<p>“In contact with” means touching at least in part.</p> <p>“In contact with” includes the presence of quickly dissolving coatings on one or other, or both, sets of particles.</p> <p>“Not in the same” means in different.</p> <p>“Particle” means small piece or fraction.</p>	<p>Actavis agrees that “not in the same” means “in different”.</p> <p>Notwithstanding this term, the full claim limitation is indefinite.</p>
<p>“<u>particles of citric acid</u> are presented and act as carrier particles”¹</p> <p>(claim 6)</p>	<p>Reference to “particles comprising citric acid” in claim 1.</p>	<p>Indefinite.</p>

¹ Underlining presented by Actavis in its May 15, 2015 Preliminary Invalidity Contentions and May 20 exchange of claim terms to be construed and proposed constructions.

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